

# Early Activation of Artificial Urinary Sphincter: A Pilot study

## **Abstract:**

Urinary incontinence or loss of bladder control is a troublesome issue for all affected patients. The causes of urinary incontinence and its treatment options vary widely. A commonly encountered reason for urinary incontinence in men is related to treatment for prostate cancer. These treatment options can range from surgical removal of the prostate, external beam radiation therapy, and/or brachytherapy, the insertion of radioactive implants directly into the tissue. Mild cases of incontinence are responsive to more conservative measures, but moderate to severe cases often require placement of an artificial urinary sphincter. Typically, these devices are left deactivated for a period of 4- 6 weeks following implantation to allow swelling to subside before use. We hypothesize that the device could be activated within an earlier timeframe without increasing the risk of complications. No studies to date have evaluated this; therefore we plan to conduct a prospective study in which we will activate the device 3 weeks after placement and monitor for complications.

## **Aim of the study:**

To assess the safety and feasibility of early activation of an artificial urinary sphincter and assess whether or not this increases the risk of postoperative complications. We hypothesize that a period of 3 weeks should allow adequate time for the resolution of urethral and scrotal swelling following artificial urinary sphincter placement, and that activation of the device at that time, as opposed to traditional 4-6 weeks post-operatively, will lead to improved patient satisfaction with no increase in postoperative complications.

## **Background:**

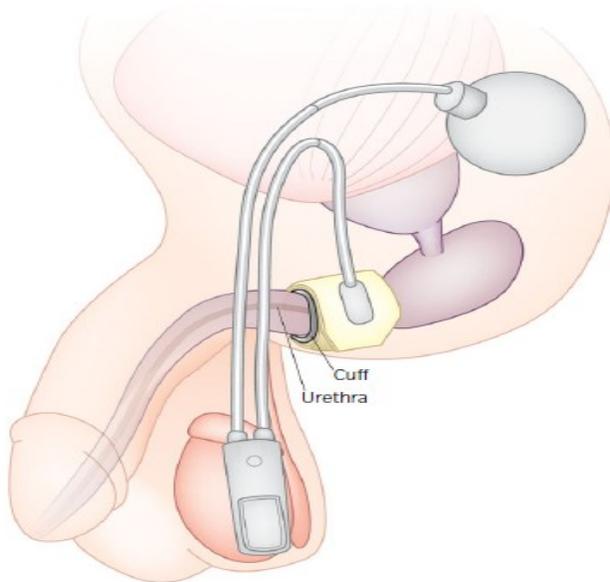
Urinary incontinence is one of the most common complications following surgical treatment of prostate cancer via radical prostatectomy. All patients will have this to some degree in the initial post-operative period, but it typically resolves over time as the newly created urethrovesical anastomosis heals. Wolin et. al reported a 59% rate of urinary incontinence at 6 weeks post-prostatectomy among studied patients<sup>1</sup>. For the unfortunate patients who have persistent incontinence requiring the use of multiple pads per day in the absence of a bladder neck contracture or stricture, an artificial urinary sphincter (AUS) may be the best option to regain continence.

The AUS was first introduced into practice in 1972 at the Baylor College of Medicine. Since that time, it has been found to effectively improve the quality of life of patients with post-prostatectomy urinary incontinence. In a recent analysis, 79% of patients report being satisfied and using no more than one pad per day<sup>2</sup>. The device has undergone numerous revisions since its introduction and the current model, the American Medical Systems (AMS) 800, is widely implanted throughout the U.S. and worldwide. Several studies have been performed validating the AUS as a surgical treatment of post prostatectomy incontinence. There have been varying degrees of success documented in the literature secondary to the different definitions of success used, however, using the definition of zero to 1 pad per day, success rates have varied between 60% and 90% in modern series(3).The most common

complication is urinary retention, which can be managed with a urethral catheter. Less common complications include infection, device malfunction, and urethral erosion<sup>3</sup>.

The device (see figure 1) is placed in the operating room under general anesthesia. The device consists of a urethral cuff, pressure regulating balloon, and an activation pump and once activated, the urethral cuff will be closed at rest. The patient will squeeze the scrotal pump to open the cuff in order to void once the need arises. Patients are typically discharged the same day without a Foley catheter, unless unable to void in the recovery room. The device is typically left in the de-activated position to allow reductions in urethral edema and scrotal edema before the patient is allowed to manipulate the device. The device is routinely activated at 4-6 weeks post-operatively<sup>4</sup>. A literature review did not reveal any papers or guidelines that show that this period of de-activation of 4-6 weeks is actually required, though Baylor College of Medicine reports current practice of only waiting 4 weeks until activation<sup>5</sup>. There have not been any studies conducted indicating any negative consequences of activating the device early and there have been two or three patients at CAMC who have activated their device a few days post discharge from the hospital, against our advice.. These patients did not report any adverse events with early activation.

There are possible complications associated with AUS placement. Complications that occur less often include bleeding, infection, urinary tract injury, device erosion, wasting away of muscle mass in the urinary tract known as sub cuff atrophy, or loss of bladder control. Complications that may occur occasionally include persistent loss of bladder control or Mechanical Failure of device. These are risks associated with any AUS procedure and patients participating in this study will not be at higher risk for these than those who chose not to participate.



**Figure 1. Implanted Artificial Urinary Sphincter (AUS) demonstrating attachments of the cuff to the pressure regulating balloon and intra-scrotal pump<sup>4</sup>.**

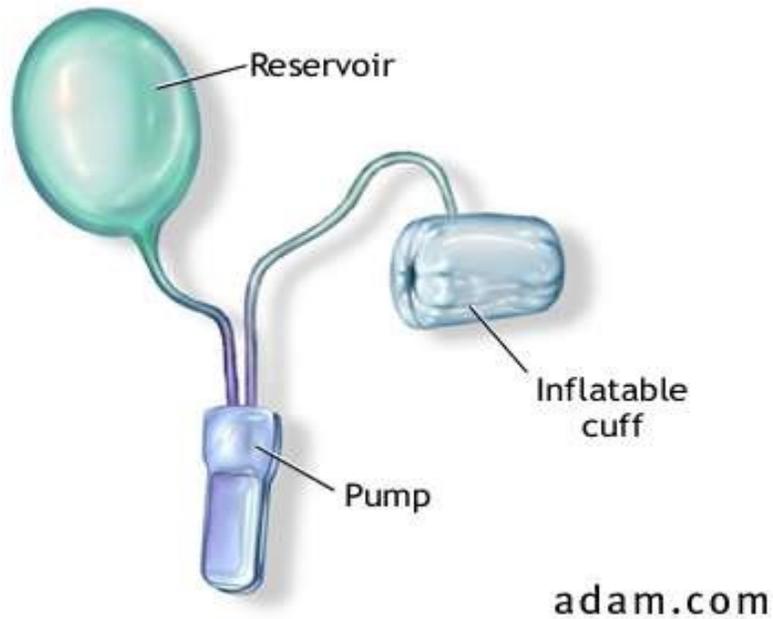


Figure 2 Artificial Urinary Sphincter (AUS)

An artificial urinary sphincter is used to treat stress incontinence in men, which is caused by urethral dysfunction (usually after prostate surgery). Additionally, this procedure is performed in both men and women with sphincter dysfunctions related to spinal-cord injury or multiple sclerosis. Before resorting to this treatment, most experts advise using medication and bladder-retraining therapy. Alternatives to this procedure include the pubovaginal sling in women, or the periurethral injection of collagen in both men and women.

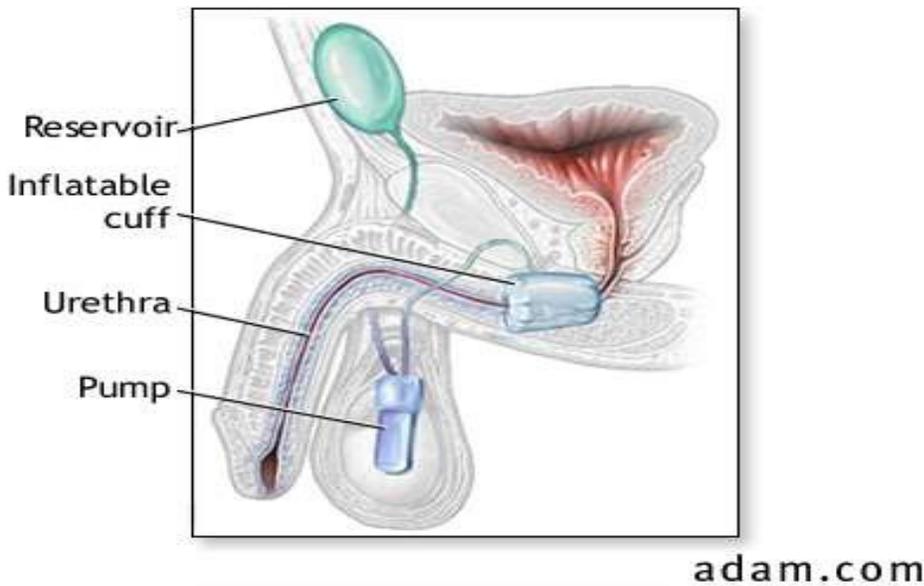
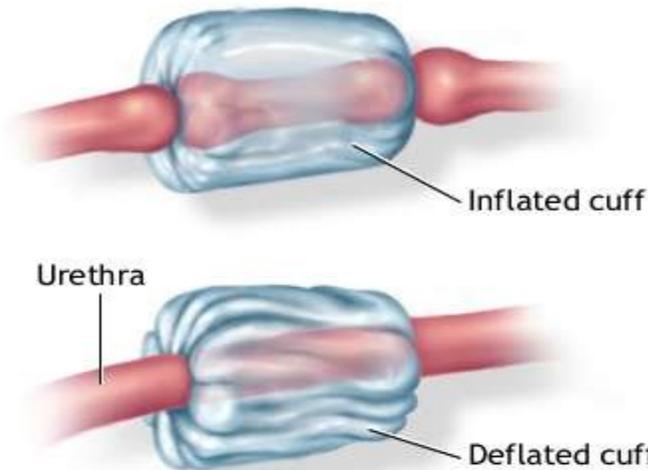


Figure 3 Implanted AUS

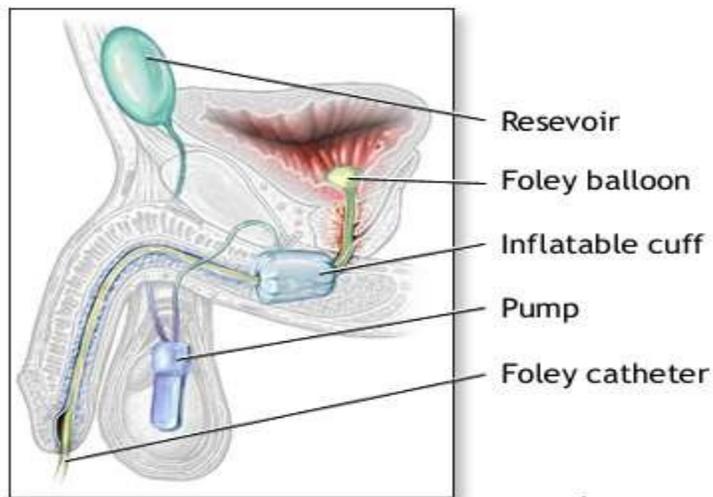
An artificial sphincter consists of: a cuff that fits around the bladder neck a pressure regulating balloon a pump that inflates the cuff to treat urinary incontinence, a cuff is placed around the bladder neck so that when it is inflated, the urethra closes tightly. The pressure-regulating balloon is placed under the tissues of the lower abdomen. The balloon is then filled with liquid (occasionally, an iodine-based solution is used so that it will be visualized when x-ray procedures are performed). The control-pump mechanism is placed in the labia for women, and in the scrotum for men. To use the sphincter, compress (squeeze) the pump so that fluid is diverted from the urethral cuff to the balloon. This action enables the sphincter to relax, which in turn, enables you to urinate. The cuff re-inflates on its own in three to five minutes.



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Figure 4 Inflation of AUS

When inflated, the cuff constricts the urethra and blocks the passage of any urine. When deflated, the cuff reduces pressure on the urethra and allows for the free passage of urine.



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Figure 5 AUS with Foley catheter

A foley catheter is also inserted during surgery, which is removed prior to discharge from the hospital. The artificial sphincter cuff is not inflated immediately after surgery, in order to allow the tissues to heal.

### **Significance:**

Post-prostatectomy urinary incontinence is a troubling complication following treatment (radical prostatectomy, radiation therapy, or brachytherapy) for prostate cancer, or in rare instances the treatment of benign prostatic hypertrophy, and significantly decreases quality of life in affected patients. An artificial urinary sphincter has been found to significantly improve quality of life in these patients. Providing data which demonstrates the safety and feasibility to activate an artificial urinary sphincter 3 weeks after surgery as opposed to 4-6 weeks will allow men to regain their continence earlier, therefore improve their quality of life.

## **Methods**

### **Study Design:**

The design will be a single institute prospective study with patients undergoing artificial urinary sphincter placement by the operating surgeon, Dr. Joshua Lohri at Charleston Area Medical Center in Charleston, WV. All patients following informed consent that meet the inclusion criteria are eligible to participate in the study.

### **Sample:**

All male patients with moderate to severe urinary incontinence who have been treated for prostate cancer (radical prostatectomy, External Beam Radiation therapy or brachytherapy, or Incontinence related to trans urethral resection of the prostate (TURP) or simple prostatectomy undergoing artificial urinary sphincter placement at Charleston Area Medical Center by Dr. Joshua Lohri, D.O. will be offered the chance to participate in this study. This is a pilot study and thus no power analysis to calculate necessary sample size is conducted to determine a number that would yield sufficient power. We will aim to enroll 25 patients, which we anticipate to be accrued within 3 years from the start of the study. We will have 1 study group: those who are activated at 3 weeks post implantation.

### **Inclusion Criteria:**

All patients undergoing artificial urinary sphincter (AUS) placement by a single surgeon, Dr. Joshua Lohri.

### **Exclusion Criteria:**

Any patient who has previously undergone artificial urinary sphincter placement and presents for revision or additional cuff placement.

Any patient who is undergoing combined artificial urinary sphincter and inflatable penile prosthesis placement.

Any patient who is a poor candidate for early activation due to poor condition at presentation or signs of infection.

### **Procedures and Protocol:**

There isn't a comparison group for this study; therefore all patients agreeing to participate will have the urinary sphincter activated 3 weeks after surgery. If there are patients that later choose not to have early activation or are found to be poor candidates for three week activation based upon their post op

exam, we will proceed with activation at a 4-6 week time period. While there is no comparison group in the study, patient satisfaction and adverse events for study patients will be compared to historical literature.

Currently patients are not routinely seen for a 3 week follow up appointment, so approximately \$3000 will be requested from Research appropriations to cover the costs of this study. All other costs are standard of care, so patient will be responsible for those costs whether they agree to enroll in the study or not. The money from the CAMC Research Appropriations will be used to cover all the clinical fees for the 3 week visit to activate the AUS.

Pre-procedure:

1. All eligible patients will be informed about the study at their regularly scheduled pre-operative office visit. If the patient agrees to participate, they will be consented with the consent form as written. A note is made in the progress note of the patient's chart detailing the consent.
2. Original signed consent will be kept and stored in the consent binder at Dr. Lohri' office and one copy of the consent will be placed in the medical record and another will be given to the participant.
3. Patient will complete an SF-8 quality of life survey and Incontinence Impact Questionnaire (Appendix A).

Intraoperative procedures:

1. Once consented, the patient will undergo the procedure without any changes to our normal routine. The patient's device will be deactivated at the conclusion of the procedure.

Post-procedure:

1. The patient will be discharged post-operatively (same day) and follow-up will be arranged in 3 weeks to activate the device.
2. Study patients have a follow up office visit at 3 weeks (up to 3 weeks and 3 days after the procedure) which includes a post-operative evaluation of their incisions, degree of bruising, tissue induration, tenderness and accessibility of the pump. If these factors are acceptable and pump mechanics are normal, the artificial sphincter will be activated and the patient will be educated on its proper use.
3. Additional follow up will include the regular 6 week visit, a visit at 3 months, and then every 6 months for a total of 1 year unless issues arise that necessitates deviation. At each visit, patients will complete the Incontinence Impact Questionnaire and the SF-8 quality of life survey.

**Study Chart:**

INFORMATION	PRE-Treatment	Intra-operative Treatment	POST-Treatment 3 weeks (up to 3 weeks and 3 days after procedure)	POST-Operative Treatment 6 weeks ( $\pm 1$ week)	POST-Operative Treatment 3 months ( $\pm 2$ weeks)	POST-Operative Treatment Six months ( $\pm 3$ weeks)	POST-Operative Treatment 1 year ( $\pm 1$ month)
Inform Subject	X						
Consent Subject	X						
Note in Record	X						
Office visit	X		X	X	X	X	X
SF-8 survey administered	X			X	X	X	X
Incontinence Impact Questionnaire	X		X	X	X	X	X
Procedure conducted		X					
<b>Data Collection</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>

**Data Collection and Management:**

The SF-8 is a quality of life instrument related to health functioning that provides an eight question brief assessment of physical and mental health<sup>6</sup>. It has been found to have adequate reliability and validity in prior studies for quality of patient life and it incorporates a manual for easy interpretation.<sup>7</sup> The Incontinence Impact Questionnaire short form was adapted from a survey that was developed for women with stress incontinence. This questionnaire has been validated for use in men after radical prostatectomies and consists of 7 items in which measures the effect of Urinary Incontinence on quality of life<sup>8</sup>.

Following surgery, patient characteristics and operative details will be recorded. These will include:

- Medical Record Number
- Patient name
- Age
- BMI
- Operative time
- Artificial sphincter cuff size
- Pressure-regulating balloon size
- Intra-operative complications (urethral injury, bleeding)
- Reason for AUS placement (Post-prostatectomy, Radiation therapy for prostate cancer, or Incontinence related to TURP)
- Finish date of prostate cancer treatment or TURP
- Preoperative daily pad usage
- Pre-surgery SF-8 survey
- History of medication
- Date device is activated
- Comorbidities
- ECOG Score

- ASA Score
- Tobacco Use
- Diabetes

When the study patient follows up at 3 weeks postoperatively, we will assess for immediate postoperative complications:

- Post-operative urinary retention Y/N
- Bleeding Y/N
- Presence/concern for infection Y/N
- Presence/concern for urethral erosion Y/N

When any patient follows up at 6 weeks, 6 months, and 12 months postoperatively, we will assess:

- Postoperative daily pad usage
- Perceived improvement in incontinence (scale 1 (none) – 10 (very satisfied))
- Presence/concern for infection Y/N
- Presence/concern for urethral erosion Y/N
- Post-surgery SF-8 surveys (6 weeks, 3 months, 6 months)

### **Statistical Analysis:**

The Center of Health Service and Outcomes Research will conduct the data analysis. For this exploratory study, selection of appropriate statistical measure will be determined by CAMC Center for Health Education and Research Institute. Specific tests will be determined by whether the data is continuous or categorical. Descriptive statistics will be used as appropriate and comparisons will be done using student's T-test and chi-square test. In addition univariate and multivariate multiple logistic regressions will be used to determine which variables predict patient's outcomes. All comparisons will be done at 95% of level of significance.

### **I. Human Subjects**

Study population: All patients undergoing artificial urinary sphincter (AUS) placement by a single surgeon, Dr. Joshua Lohri at Charleston Area Medical Center.

Recruitment methods: All patients, following informed consent, that meet the inclusion criteria are eligible to participate in the study. Patients will be consented by the principal investigator only at time of usual surgical informed consent using the attached consent form. Consent will be obtained prior to the surgical procedure.

Benefits: Early activation of the artificial urinary sphincter will allow the patient to regain continence earlier.

Risks and discomforts: The principle risks of participation in this study will be the standard risks of the operation.

Less often, there are risks of bleeding, infection, urinary tract injury, device erosion, wasting away of muscle mass in the urinary tract, or loss of bladder control.

Occasionally, there are risks of persistent loss of bladder control or mechanical failure of device.

Sexual Activity: All patients will be asked to refrain from sexual activity for 4-6 weeks following surgery, which is our current standard post-operative course.

Consent Process: Dr. Joshua Lohri will consent eligible patients at their office visit prior to scheduling the procedure. Patients will be educated on the study and told that if they do not wish to participate, they will receive the usual care which is activation of device at the 6 week checkup.

Confidentiality: Taking part in this research study requires doctor and assistants to review all medical records as may be needed for purposes of this study. Any release of information derived from these medical records to scientific organizations, medical journals, etc. will be done only without identification of the study participants. All study records will be held in strict confidence. Patient's records may be inspected by governmental agencies such as the DHHS, including FDA, and CAMC/WVU Institutional Review Board. They may inspect patient's records for the purposes of this study and/or audit while maintaining your records as confidential to the extent required by the law. The results of this research study may be presented at meetings or in publications. Patient's identity will not be disclosed in those presentations.

Costs to subjects: There will be no additional costs associated with patient's participation in this study. Costs for additional visit at 3 weeks to activate the AUS will be covered from grant funding requested from the CAMC Research and Grants Office's Research appropriations. Patient will accrue no costs for participation in this study. Routine costs will be billed in the customary manner. We do not anticipate any additional cost to the patient.

Payments to subjects: There will be no payments to subjects for participating in this study.

Debriefing: If the patient chooses not to participate in the study then he will receive the current management which includes office follow-up at 4-6 weeks postoperatively for activation of the device.

Intervention: Patients will be offered pilot study enrollment if they meet the inclusion criteria. They will be asked to complete the SF-8 and Incontinence impact questionnaires at their initial office visit when they are consented and then at their 6 week, 3 month and 6 month follow up visits. Patients in the study group will have an additional visit, at no cost to them at 3 weeks for early activation of the urinary sphincter. Other than an extra office visit for the study group and the completion of the questionnaires at their office visits, treatment will be the same for those that agree to participate as those who do not participate in the study.

### **Participants:**

Joshua Lohri, DO is the principal investigator. He completed a fellowship in reconstructive urology, female urology, and urodynamics at Duke University Medical Center from 2011-2012 and is qualified to conduct this research. His research interests include urinary incontinence and dysfunctional voiding.

Sharon Hill, MPH is a research associate senior with the Center for Health Services and Outcomes Research working closely with the urology residency program at Charleston Area Medical Center.

Lisa Calderwood is a research assistant II with the Center for Health Services and Outcomes Research.

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# Incontinence Impact Questionnaire – Short Form IIQ-7

Some people find that accidental urine loss may affect their activities, relationships, and feelings. The questions below refer to areas in your life that may have been influenced or changed by your problem. For each question, circle the response that best describes how much your activities, relationships, and feelings are being affected by urine leakage.

Has urine leakage affected you:

	Not at All	Slightly	Moderately	Greatly
1. Ability to do household chores (cooking, housecleaning, laundry)? .....	0	1	2	3
2. Physical recreation such as walking, swimming, or other exercise? .....	0	1	2	3
3. Entertainment activities (movies, concerts, etc.)? .....	0	1	2	3
4. Ability to travel by car or bus more than 30 minutes from home? .....	0	1	2	3
5. Participation in social activities outside your home? .....	0	1	2	3
6. Emotional health (nervousness, depression, etc.)? .....	0	1	2	3
7. Feeling frustrated? .....	0	1	2	3

Items 1 and 2 = physical activity  
Item 5 = social/relationships

Items 3 and 4 = travel  
Items 6 and 7 = emotional health

**Scoring.** Item responses are assigned values of 0 for "not at all," 1 for "slightly," 2 for "moderately," and 3 for "greatly." The average score of items responded to is calculated. The average, which ranges from 0 to 3, is multiplied by 33 1/3 to put scores on a scale of 0 to 100.